


TFW 1625

Patent

Attorney Docket No. 1662/55002

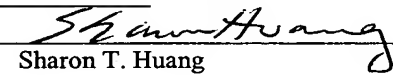
			
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE			
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		Docket Number: 1662/55002	
Application Number 10/016,752	Filing Date October 30, 2001	Examiner Taylor V. Oh	Art Unit 1625
Invention Title NOVEL CRYSTAL AND SOLVATE FORMS OF ONDANSETRON HYDROCHLORIDE AND PROCESSES FOR THEIR PREPARATION		Inventors Ramy Lidor-Hadas et al.	

Mail Stop Amendment
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Date: Feb. 27, 2006

Signature: 
Sharon T. Huang

Sir:

1. In accordance with the duty of disclosure under 37 C.F.R. § 1.56 and in conformance with the procedures of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, attorneys for Applicants hereby bring the following references to the attention of the Examiner. These references are listed on the attached modified PTO Form No. 1449. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. The filing of this Information Disclosure Statement and the enclosed PTO Form No. 1449, shall not be construed as an admission that the information cited is prior art, or is considered to be material to patentability as defined in 37 C.F.R. § 1.56(b).
2. Copies of patents, publications or other information listed on the modified PTO Form 1449 are enclosed, unless indicated otherwise.

3. It is believed that no fees are due in connection with this Information Disclosure Statement. However, should any fees be due the Commissioner is authorized to charge deposit account number 11-0600 for such fees.

Respectfully submitted,

Date: 2/27/06



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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/016,752
Filing Date	October 30, 2001
First Named Inventor	Ramy Lidor-Hadas et al.
Art Unit	1625
Examiner Name	Taylor V. Oh
Attorney Docket Number	1662/55002

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		4,739,072	04-19-1988	Oxford et al.	
		4,783,478	11-08-1988	Wootton et al.	
		4,835,173	05-30-1989	Tyers	
		4,957,609	09-18-1990	Godfrey et al.	
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		5,629,333	05-13-1997	Young	
		5,712,302	01-27-1998	Young	
		5,854,270	12-29-1998	Gambhir	
		5,962,494	10-05-1999	Young	
		6,063,802	05-16-2000	Winterborn	
		6,388,091	05-14-2002	Lee et al.	
		2004/0019093	01-29-2004	Aronhime et al.	
		2005/0020655	01-27-2005	Molnar et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		EP 0 276 559 B1	08-03-1998	Tyers		
		EP 0 415 522 B1	03-06-1990	Collin		
		WO 02/36558 A2 (U.S. equivalent 2002/0107275)	05-10-2002	Lidor-Hadas et al.		
		WO 02/055492 A2 (U.S. equivalent 2002/0115707)	07-18-2002	Lidor-Hadas et al.		
		WO 03/090730 A1	11-06-2003	Ndzie et al.		

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Sheet 2 of 2

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Application Number	10/016,752
Filing Date	October 30, 2001
First Named Inventor	Ramy Lidor-Hadas et al.
Art Unit	1625
Examiner Name	Taylor V. Oh
Attorney Docket Number	1662/55002

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Pirttimaki, J., et al. "The Transformation of Anhydrate and Hydrate Forms of Caffeine at 100% RH and 0% RH, <i>European Journal of Pharmaceutical Sciences</i> , 1994, Vol. 1, pp. 203-208	
		Iida, H., et al. "Intramolecular Cyclization of Enaminones Involving Arylpalladium Complexes. Synthesis of Carbazoles" <i>J. Org. Chem.</i> 1980, Vol. 45, pp. 2938-2942	
		European Pharmacopoeia 4.4, Ondansetron Hydrochloride Dihydrate" 2003, pp. 3489-91,	
		Harry G. Brittain (Ed.) (1999) "Polymorphism in Pharmaceutical Solids" <i>Drugs and the Pharmaceutical Sciences</i> Vol. 95, pp. 183-226, Marcel Dekker, Inc. New York, New York	
		Bym, S.R., et al. (Ed.) (1999) "Solid-State Chemistry of Drugs" Second Edition, pp. 59-67, SSCI, Inc. West Lafayette, Indiana	
		Bym, S.R., et al. (Ed.) (1982) "Solid-State Chemistry of Drugs" pp. 6-7, Academic Press, New York, New York	
		Threlfall, T.L., et al. "Analysis of Organic Polymorphs" <i>The Analyst</i> , 1995, Vol. 120, pp. 2435-2460	
		Carlless, J.E., et al. "Cortisone acetate crystals forms" <i>J. Pharm. And Pharmacology</i> , 1966, Vol. 18, pp. 190S-197S	
		Chen, Chem Abstr., "Synthesis of Antiemetic Ondansetron" <i>Chinese J. of Pharmaceuticals</i> , 1993, 24(6), pp. 241-242 (Ch).	
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		The United States Pharmacopeia (USP 27-NF22), 22 nd edition, Second Supplement, August, 2004, pages 3234, 3283-3285	
		The United States Pharmacopeia (USP 26-NF21), 21 st edition, The National Formulary, January, 2003, pages 1351-1352	
		The Merck Index p. 6977 "Ondansetron", 1996	
		Kim, M. Y, et al. "An Efficient Process of Ondansetron Synthesis" <i>Heterocycles</i> , 1997, Vol. 45, No. 10, p. 2041-2043	

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